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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,969	12/03/2001	Stephen Bresina	2678	7840
530	7590	02/18/2004	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			PHILOGENE, PEDRO	
			ART UNIT	PAPER NUMBER
			3732	//

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,969

Applicant(s)

BRESINA, STEPHEN

Examiner

Pedro Philogene

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5 and 7-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5 and 7-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 7, 10-12, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bresina et al. (6,395,035) in view of Williams et al (6,113,638).

With respect to claim 1, Bresina et al disclose an apparatus for facilitating fusion of adjacent vertebrae, comprising an implant (1) body dimensioned for positioning within an intervertebral space between upper and lower vertebrae to maintain the vertebrae in desired spaced relation to facilitate fusion thereof, the implant body including lower and upper surfaces for engaging respective lower and upper vertebrae, and first and second side wall portions; as best seen in FIGS. 5,6; extending between the upper and lower surfaces, the first and second wall portions being substantially solid, at least one of the first and second side wall portions having a substantially narrow longitudinal slit (8) defined therein arranged to enhance flexibility of the side wall portion.

It is noted that Bresina et al did not teach of an implant body including two or more bores extending through the upper and lower surfaces for reception of bone growth inducing substances, the bores in communication with the slit, as claimed by applicant. However, in a similar art, Williams evidences the use of an implant having two or more bores (103) extending through the upper and lower surfaces for reception of

bone growth inducing substances, the bores in communication with the channel (105) for receiving bone graft material therein.

Therefore, given the teaching of Williams, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Bresina et al., as taught by Williams, with two or more bores in upper and lower surfaces, in communication with the slit of Bresina et al., to provide a passage for receiving bone growth inducing material therein.

With respect to claims 2,5, 7,10-12, the above combination of references discloses all the limitations, as set forth in columns 4-6, lines 1-67; and as best seen in FIGS. 1-11 of Bresina et al., and as set forth in column 7, lines 33-46; and as best seen in FIG. 5A of Williams.

With respect to claims 14-17, the method steps, as set forth, would have been obviously carried out in the operation of the device, as set forth above.

Claims 20-22,24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heggeness et al (5,514,180) in view of Williams et al. (6,113,638).

With respect to claim 20, 24, Heggeness et al discloses a kit for fusion of adjacent vertebra comprising a plurality of implants (60,70,80,90,100), each having an implant body including an upper and a lower surfaces for engaging respective adjacent vertebra and sidewall position extending between the upper and lower surfaces and surrounding an internal cavity having plurality of generally cylindrical internal bores open to the upper and lower surfaces; as best seen in Fig.25; a plurality of bone plugs,

as set forth in column 11, lines 40-49, sized to fit into each of the cylindrical internal bores.

It is noted that Heggeness et al. did not teach of bores having sides in open communication with adjacent bores, as claimed by applicant. However, in a similar art, Williams et al evidence the use of an implant having at least three bores (103) with sides in open communication with adjacent bores; as best seen in FIG.5A adapted to receive bone growth material.

Therefore, given the teaching of Williams et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Heggeness et al., as taught by Williams to provide an implant with at least three bores in open communication with adjacent bores adapted to provide a passage for receiving bone growth inducing material therein.

With respect to claims 21-22, Heggeness et al disclose all the limitations, as set forth in column 11, lines 40-49 and as best seen in Fig.25.

Claims 18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bresina et al (6,395,035) in view of Williams et al. (6,113,638) in view of Heggeness et al. (5,514,180).

With respect to claims 13,18,19, it is noted that the above combination of references did not teach of a plurality of internal bores, further including bone plug; as claimed by applicant. However, in a similar art, Heggeness et al. (FIG.25) evidences the use of an implant with a plurality of internal bores and including bone plug to facilitate bone growth.

Therefore, given the teaching of Heggeness et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the plurality of internal bores filled with bone plug, as taught by Heggeness et al., in the device of Bresina/Williams et al to facilitate bone growth.

Claims 8,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bresina et al (6,395,035) in view of Williams et al., (6,113,638) in view of Biscup (6,245,108).

With respect to claims 8,9, it is noted that Bresina the above combination of references did not teach of a plurality of ridges and grooves on the upper and lower surfaces of the implant; as claimed by applicant. However, in a similar art, Biscup evidences the use of an implant with ridges and grooves on top and bottom surfaces to engage the surface of an adjacent vertebra.

Therefore, given the teaching of Biscup, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate ridges and grooves on the upper and lower surfaces of the device of Bresina/Williams et al to engage the surface of an adjacent vertebra.

Claims 23,25,26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heggeness et al (5,514,180) in view of Williams et al. (6,113,638) in view of Bresina et al. (6,395,035).

With respect to claim 23,25,26, it is noted that the above combination of references did not teach of an implant body including slit in the sidewall in communication with the bore, as claimed by applicant. However, in a similar art, Bresina

et al evidence the use of an implant with a slit in the sidewall in communication with a bore to provide an implant that absorbs stress transfer by the cage to the graft material.

Therefore, given the teaching of Bresina et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Heggeness/Williams et al., as taught by Bresina et al to provide an implant that absorbs stress transfer by the cage to the graft material.

Response to Amendment

Applicant's arguments filed 12/10/03 have been fully considered but they are not persuasive. Applicant stated that none of the references teaches of a plurality of bores forming the cavity in the implants. However, Williams et al., evidences the use of an implant with a plurality of bores and being in communication with adjacent bores. Furthermore, Bresina et al teach of a slit in communication with a bore forming the central cavity, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8., it would have been obvious to one having ordinary skill in the art at the time of the invention to duplicate the bore of Bresina et al. to arrive at a plurality of bores, as claimed by applicant.

Conclusion

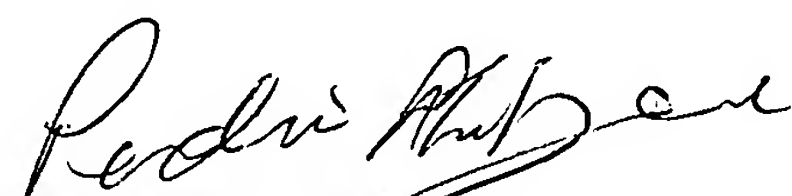
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

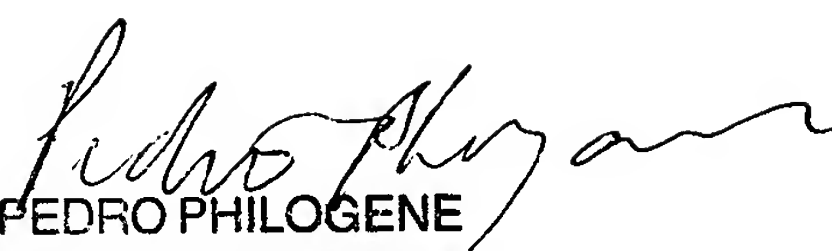

PEDRO PHILOGENE
PRIMARY EXAMINER

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Pedro Philogene
February 13, 2004


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